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Summary Report of the first European Exposure Science Strategy Workshop: Building a Roadmap 2020-2030

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This publication is a Technical report by the European Chapter of the International Society of Exposure Science (ISES Europe), which is a regional chapter of ISES. The objective of ISES Europe is to foster and advance exposure science needed to safeguard European citizens from environment-related pressures and risks for health and well-being. **The contents of this report do not imply any position of the authors nor the listed institutions.** Neither ISES Europe nor any person acting on behalf of ISES Europe nor the listed institutions are responsible for the use of this publication. For further information visit http://ises-europe.org/html/about.html (ISES Europe) or https://www.intlexposurescience.org (ISES).

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Finally, ISES Europe wants to express its gratitude to all workshop participants and their home institutions for their valuable inputs provided during the workshop. Assessing and combining all opinions expressed into a report of assessment needs for a European Strategy on Exposure Science and deriving recommendations has been a challenging, but rewarding task. This report represents a first and essential step for building and advancing the development of the strategy with a roadmap 2020-2030.

Summary

European legislations create unique demands for the European exposure science community. Human and environmental exposure assessments for chemicals are required as part of the risk assessments undertaken in the context of various legislations (e.g. under REACH, the Biocides Regulation, the General Food Law but also the Regulation on Medical Devices and Construction Products). In addition, regulations on general product safety, classification, labelling and packaging, control of air quality and major-accident hazards require input on exposure. Moreover, security-driven exposure assessments are being increasingly requested related to the misuse of chemical biological radiological and nuclear (CBRN) materials. Knowledge gaps, method and tool limitations, new needs together with longer-term EU strategies and several new trends all add additional challenges to the field of exposure science calling for the development of a *European Strategy for Exposure Science*. New trends that can be used as a starting point are for example:

- Exposure science offers much more enhanced knowledge and methods than is currently implemented in regulatory risk assessments.
- Further public rejection of using animals for safety testing of chemicals increases the dependency on exposure assessment.
- Growing appreciation of the importance of interactions between man and the environment in a globalised economy (e.g. green and/or circular economy, management of global supply chains and the contained chemicals, sustainability, biodiversity).
- Exposure to various chemicals at the same time and aggregate exposure to one chemical from different sources are increasingly recognised as requiring assessment, but neither the exposure data nor the assessment methods are available at present.

As a first step of strategy building, the first workshop of the European Chapter of the International Society of Exposure Science (ISES Europe) took place on June 19-20, 2018 in Dortmund, Germany, hosted by the German Federal Institute for Occupational Safety and Health (BAuA). The main objectives of this workshop were: (1) to design the backbone of *The European Exposure Science Strategy* with a roadmap 2020-2030; (2) to create working groups with their own goals and agenda in alignment with the overall strategy; (3) to identify actions for further research and policy needs in Europe; and (4) to attract ISES Europe members committed to contributing to build the strategy and to increase the visibility of exposure science in Europe.

The workshop was structured around six thematic areas that were identified on the basis of a stakeholder survey on needs for exposure science in Europe. These thematic areas were:

1. Data repositories and analytics,
2. Regulatory exposure assessment
3. Exposure data production and monitoring
4. Building partnerships and collaboration
5. Exposure assessment methods and tools
6. Exposure science education and communication

On the first day, the focus was on assessing the needs, gaps and opportunities for exposure science in Europe, and on the second day, the focus was on identifying building blocks for fulfilling the identified needs. Both days started with keynote lectures and continued with thematic parallel working group sessions along the defined thematic areas.

About 120 experts working at nine stakeholder groups participated in the workshop comprising European Commission Services, European Agencies, European Member States' national authorities, industry, academia, consultants and insurance companies.

During the breakout sessions, interactive discussions took place where exposure science practitioners discussed strategic activities and domains relevant for defining a strategy for exposure science to better serving human health and wellbeing, environmental safety needs, inform exposure policy domains, and help product developers and sustainability managers to achieve their goals towards a sustainable development in Europe. The workshop defined building blocks and actions, comprising e.g. the creation of working groups, and initiation of projects responding to the identified needs, concerning exposure science and relevant policies, and the level of coordination needed between the various stakeholders involved in the exposure science-policy interface.

It was concluded that the following building blocks and actions are needed as a foundation of a European Exposure Science Strategy being:

1. To establish a common portal on exposure science,
2. To build a European exposure science network and partnerships,
3. To develop a common framework across policies and regulations making use of exposure science by focussing on the alignment of principles and efficiency enhancement,
4. To establish an integrated exposure assessment framework of methods and tools, and
5. To develop an education and training scheme.

The present report summarises the workshop's outcome and represents a first step towards the development of a European Exposure Science Strategy with a roadmap 2020-2030.

The report is structured in a way that it first briefly introduces exposure science and its role for the European community (Chapter 1), followed by an overview of the first ISES Europe workshop organization (Chapter 2), the workshop outcome (Chapter 3), and a related brief discussion and some conclusions (Chapter 0). In the appendix, we provide the workshop agenda (Appendix A), a list of participants' affiliations (Appendix B), names of session chairs, co-chairs, rapporteurs and moderators (Appendix C), the results of the SWOT analyses of the thematic breakout sessions (Appendix D), and a list of posters presented during the workshop (Appendix E).

1 Introduction

1.1 What is exposure science and how does it contribute to a healthy environment and to a safe and secure society?

Exposure science aims to help understanding the mechanisms and extent to which humans or ecological receptors are exposed to stressors as well as understanding the situations posing a potential risk to human or environmental health. Stressors commonly refer to chemical, biological, radiological and nuclear (CBRN) agents or materials (European Commission, 2009; EU Centres of Excellence on CBRN, 2018), physical phenomena (noise), but also psychological and social phenomena (Senier et al., 2016).

To address potential risks caused by these stressors, it is important to understand stressor related hazards (man-made and natural) that may lead to unwanted health and environmental effects while also addressing safety and security aspects (OECD, 2011), and sustainability aspects (OECD, 2011; Lioy and Smith, 2013). Both exposure and hazard assessments are indispensable parts of risk assessment and management strategies, and related analyses, such as impact assessments and socio-economic analyses (National Research Council, 2012).

According to the European Chapter of the International Society of Exposure Science (ISES Europe), "Exposure Science" in its broadest sense studies '*the contact between stressors (primarily chemical, biological, and physical agents) and receptors (e.g. molecules, cells, organs, humans, other living organisms, and non-living items like buildings), and the associated pathways and processes potentially leading to negative effects on human health and the natural and built environment*' (Bruinen de Bruin et al., 2019). In particular regarding chemicals, exposure science needs to integrate knowledge about their uses, i.e. the occurrence of substance in products and processes.

Exposure science supports a better understanding of stressor-health relationships, but also provides choices to be made by stakeholders comprising scientists, citizens, policy-makers and exposure science practitioners in support of their work for a safer, more sustainable and more resilient society. It can speed up urgently needed changes in society including the transition towards affordable and clean energy and the implementation of many others of the United Nations' Sustainable Development Goals (UN SDGs). Furthermore, it provides information related to impact assessments and the application of risk prevention measures due to potential deliberate misuse of CBRN materials and possible natural disasters.

The availability of good quality and reliable exposure information is crucial. The current EU Regulation on chemicals management, REACH, created a mandate to deliver adequate exposure information to foster the safe use and management of chemicals (Regulation (EC) No 1907/2006). Exposure information is also required in a multitude of other European regulatory frameworks such as the General Food law, the Stockholm Convention on Persistent Organic Pollutants (Stockholm Convention on Persistent Organic Pollutants, 2009), the Rotterdam Convention on the promotion of shared responsibilities in relation to importation of hazardous chemicals (Rotterdam Convention, 2015), the Basle Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (Basel Convention, 1995); the Seveso Directive on the control of major-accident hazards involving dangerous substances (Directive 2012/18/EU); Plant Protection Products Regulation (EC 1107/2009), Biocidal Products Regulation (EU No 528/2012); Protection of Workers Directive (2017/2398); Construction Products Regulation (EU No 305/2011); General Product Safety Directive (2001/95/EC); Classification, Labelling and Packaging Regulation (EC No 1272/2008);

Medical Devices Regulation (EU 2017/745), Industrial Emissions Directive (2010/75/EU), Waste Framework Directive (2008/98/EC), and the Air Quality Directive (2008/50/EC).

Furthermore, EU strategies to move towards a non-toxic environment by 2050 (Decision No 1386/2013/EU), to strive towards a bio-based and circular economy (European Commission, 2012 and 2015), as well as to promote green and sustainable chemistry all represent additional challenges requiring adequate exposure information.

1.2 Why is a European strategy and roadmap needed?

Regulatory changes in the EU during the last decade increased the demand for high-quality exposure information in Europe more than elsewhere. However, in the case of insufficient or missing exposure information, default values and assumptions are frequently used. These are often not well underpinned, which can lead to incorrect risk estimates due to under- or overestimations of exposures and related risk, which hampers decision-making.

Diverse parts of legislation put unique demands on the European exposure science community, such as knowledge gaps, method and tool limitations, new needs together with longer-term EU strategies and several new trends all add additional challenges to the field of exposure science. New trends that can be used as starting point are for example:

- Exposure science offers much more enhanced knowledge and methods than is currently recognised in regulatory risk assessments.
- Further public rejection of using animals for safety testing of chemicals increases the dependency on exposure assessment.
- Growing appreciation of the importance of interactions between man and the environment in a globalised economy (e.g. green and/or circular economy, management of global supply chains and the contained chemicals, sustainability, biodiversity).
- Exposure to various chemicals at the same time and aggregate exposure to one chemical from different sources are increasingly recognised as requiring assessment, but neither the exposure data nor the assessment methods are available at present.

In Europe, exposure science is closely related to regulation, because a large part of exposure science is driven by regulatory needs. However, recent scientific advances face difficulties in finding their way into regulatory common practices. To address this issue in relation to European exposure science, professionals representing a wide range of stakeholders met and agreed that it was time to join forces and to work together building an urgently needed *European Strategy for Exposure Science*, and a related community. In 2017, ISES Europe was founded and strives to work out the best way to promote advancements of exposure science in Europe. Given the recent regulatory and non-regulatory developments, it is considered timely to ensure that exposure science is recognized by the European stakeholders as an independent field of science that requires specific advancements and harmonization across regulations and sectors.

Multiple actors in the field expressed the need to have guidance to enhance transparency of choices made in the selection of exposure-related input data, and to better understand the representativeness and other quality aspects of monitoring data and model results. Further, substantiating the use of exposure science in health, safety and security-related regulatory actions requires stakeholders to collaborate on issues of outstanding importance, such as

1. Closing the most important gaps in knowledge (prioritized by their impact on human health and the environment),
2. Increasing efficiency and effectiveness of science organisation and management,
3. Development of education and training to broadly implement exposure science as an integral part of a safety/security culture at various levels including product development, safety and security of workplaces, emission minimisation from products, installations and services, etc.

To formalize collaboration in support of addressing the above-listed challenges and goals, on June 19-20, 2018, ISES Europe organized a workshop involving European exposure science professionals from academia, industry, public stakeholder groups, insurance companies, and regulatory authorities (national and EU level). The overarching goal of the workshop was to assess the needs as a first step to develop a European strategy for promoting exposure science in support of public and environmental health research, safety and security practices and policy-making.

2 Workshop Organization

2.1 Workshop background and focus areas

During the ISES 2016 Conference in Utrecht, The Netherlands, and prior to the ISES Europe workshop in Dortmund, Germany, two separate surveys were conducted targeting exposure science professionals that represent a wide spectrum of stakeholders. The first survey conducted in 2016 was sent to all participants (560) of the ISES 2016 Conference asking to indicate where exposure science should stand in five and 10 years, respectively. In addition, conference participants could indicate what their main drivers were to work in the field of exposure science and how a European chapter could contribute to better support a more efficient implementation of the exposure science work and uptake of related methods and results into policies.

The second survey conducted in 2017 was sent to 720 European exposure science practitioners asking to provide ISES Europe with a top five priority on topics that are considered of key importance for shaping the Exposure Science in Europe until 2030.

The outcomes of both surveys were pooled and categorised using text analysis software in addition to expert judgement. On this basis, six thematic exposure science focus areas were identified:

1. Data repositories and Analytics
2. Regulatory exposure assessment
3. Exposure data production and monitoring
4. Building partnerships and collaboration
5. Exposure assessment methods and tools
6. Exposure education and communication

During the two-day workshop on June 19-20, 2018, two blocks of three parallel sessions across the aforementioned six thematic areas took place and discussed in breakout groups. Prior to these breakout sessions the working definition of exposure science drafted by the ISES Europe Board was presented and discussed. On the first day, focussing on each thematic exposure science area, the needs, gaps and opportunities for exposure science in Europe were assessed. The sessions of the second day aimed to identify the main building blocks which are essential to fulfil the identified needs as well as to identify actions including future research and policy needs, technologies, scientific support and methodologies. Both days started with keynote lectures of leading experts from the European Commission's DG Environment, Shell/Ecetoc, University of Surrey and the Institute for Risk Assessment Sciences of the University of Utrecht, each providing a unique overview on exposure science from different perspectives. In total, 119 participants actively discussed the key needs and key building blocks required to develop a European Strategy for Exposure Science with a Roadmap 2020-2030.

The strategic cycle of activities related to building and implementing a European Exposure Science Strategy is illustrated in Figure 1. The first ISES Europe workshop identified the needs and building blocks comprising working groups, actions and projects development. These results will feed into a second workshop with the aim to translate them into a concrete action plan entailing the prioritisation of needs, actions and project development with an indication of the timelines by which the needs should be fulfilled. Both the needs assessment and the action plan will shape the final content of the European Exposure Strategy with a roadmap 2020-2030. Based on this strategy, the stakeholders and working groups will work on a number of project implementations. The outcome of each project implementation will be assessed against its impact with regard to the enhancement of exposure science in Europe and will be made available in various forms (e.g. exposure guidelines and tools, databases, and trainings, etc.).

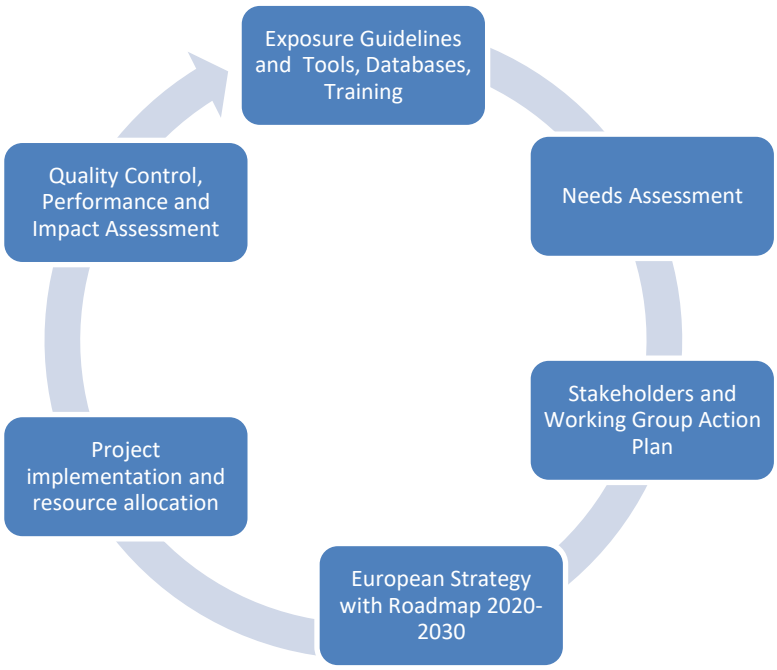

Figure 1. The Strategic Cycle of activities for building and implementing a *European Exposure Science Strategy*.

Throughout the workshop, participants were asked to think critically about the exposure science strategic analysis including assessment of the strengths, weaknesses, opportunities and threats (SWOT) for each of the six thematic exposure science areas.

2.2 Workshop Materials

In the preparatory phase of the workshop, several documents and setups were developed to manage and streamline the discussions during the plenary and breakout sessions and to facilitate the reporting of intermediate and final results during and shortly after the workshop, respectively.

- Workshop Agenda: The workshop agenda is included in Appendix A.

- Workshop participating institutions: The institutions and companies that participated to the workshop are listed in Appendix B.
- Workshop organisation: Session chairs, co-chairs, and rapporteurs were approached by the ISES Europe board, and prepared the breakout groups assisted by an ISES Board Member acting as moderator of a breakout session (Appendix C).
- Workshop outcome: Summary of the SWOT (Strengths, Weaknesses, Opportunities and Threats) analysis, the Key Needs and Building Blocks for developing a European Exposure Science Strategy are included in Appendix D.
- Workshop posters: List of posters presented during the ISES Europe 2018 Workshop (Appendix E).

3 Workshop Outcome

This chapter summarizes the results of the workshop. The following sections were developed using participants' input, discussions, recorded notes and the completed summary tables as provided during the workshop.

3.1 Exposure Science Trends

The European Strategy for Exposure Science should, amongst others, address the following topics that have a major impact on exposure science:

1. Exposure science elements are embedded in numerous documents of various European policy regulations and strategies demonstrating the importance and use of exposure science. However, despite its relevance, exposure science is often not recognised and acknowledged as an independent and self-standing scientific discipline.
2. Assessing of human and environmental health risks is currently recognised as requirement for an increasing number of stressors. Examples for which accurate assessment methods and data are currently lacking include chemical mixtures and aggregate exposures,
3. Low public awareness of possible risks from chemicals and other stressors.
4. Increasing acceptance by governments and their agencies of the concept of exposure-driven risk assessment for ensuring safety and security of the human population and the environment with decreasing dependency on use of animals testing.
5. Growing appreciation of the importance of interactions in a globalised economy between human health and the environment as well as anthropogenic impacts on the biosphere (green economy, sustainability, biodiversity, etc.).
6. Expansion of requests for and higher dependency on monitoring as such and by EU and global conventions and regulations (Stockholm Convention, Basel Convention, Rotterdam Convention, Minamata Convention, etc.).
7. Innovations in exposure assessment methodologies with application of cross-cutting assessment methodology. Exposure science offers much more knowledge and methods than is currently recognized by regulatory risk assessments.
8. Developing communication strategies and material to facilitate efficiency and transparency in sharing data, knowledge and harmonised method development.

3.2 Exposure Science Strategic Analysis

A strategic analysis for exposure science and related scientific and policy fields was performed by identifying the strengths, weaknesses, threats and opportunities (SWOT). The results are tabulated and presented in Appendix D. In addition, a general SWOT diagram for exposure science was derived

of the recurring themes identified across the individual parallel sessions of the Workshop. The results are summarised below.

Strengths

1. Exposure science is multi-disciplinary and relies on and merges a multitude of different expertise such as environmental science, health sciences, consumer protection, security science and occupational safety.
2. Data sharing initiatives do exist including improved communication between various actors, data availability, and publicly accessible data platforms and evolving repositories.
3. Increase in exposure and risk-based regulations in Europe requires good use of exposure data in risk assessment practices.
4. A large number of tools useful for supporting exposure assessment practices is increasingly becoming available.
5. Increased support and improved understanding of the concentration burden and properties of chemicals and mixtures of chemicals in various media (environment, food and feed, products and indoor air human biomonitoring) through the data that are made available by the European Commission's Information Platform for Chemical Monitoring (IPCHEM).
6. Emerging evolution of Exposome related research: initiating large multidisciplinary research programmes where the starting point is to assess the role of lifetime exposure to combined stressors regarding the human burden of disease. Research has strong focus on advancing the field with innovative technology, digitalisation, use of big data, etc.
7. Promising and recent advances in analytical methods that have provided new information on exposure to and related effects from previously unknown chemicals.
8. There are educational resources on various aspects of Exposure science available across Europe, however, they have not yet been consolidated via mainstream educational programmes (BSc, MSc and PhD level courses) Europe-wide.

Weaknesses

1. Low profile of exposure science in Europe in regulatory, academic, industrial and supply chain circles, mainly due to (a) emphasis by regulatory bodies (concerned with chemicals and their human and environmental impacts) on hazard rather than risk and consequently, exposure data is not regarded as important, (b) few universities in Europe offer exposure science programmes and there are few if any dedicated academic Departments or Schools, and academic research is very limited, and (c) lack of or partial understanding of the overlapping with exposure science of the focus areas of other scientific disciplines which are better embedded into and accepted by regulatory, academic, industry and supply chain circles (e.g. e.g. occupational hygiene, human or environmental risk assessment or, environmental health, analytical chemistry, and forensic science).

2. Lack of a well-recognised set of standards for sampling, analyses, use of tools and data reporting, as reflected in the many publications underreport data or lack experimental details.
3. Absence of frameworks for exposure assessment in many regulatory guidelines (e.g. substances of unknown or variable composition, complex reaction products or biological materials (UVCB) and aggregate exposure).
4. Major deficiencies in the data on the uses and disposal of chemicals of interest from a human health and environmental perspective.
5. Major deficiencies for all aspects of training, research, definition of needs for non-chemical stressors.

Opportunities

1. The development of ISES Europe enables a much stronger single voice for exposure science in Europe.
2. A common exposure quantification and assessment framework across regulations will stimulate data and methodologies sharing and transparency in their use.
3. Growing pressure on regulatory bodies to speed up the assessment of chemicals and to reassess old assessments based on quality data and exposure-based evidence.
4. Better involvement of and collaboration between European Commission Services and EU agencies is needed in exposure based assessments – e.g. on the UVCB substances
5. To date there are an increasing number of sample banks available that could provide opportunities for analysis of the history of sites of interest (e.g. in terms of pollution).
6. Increasing recognition that changes in human health and environment can be traced and quantified by the use of exposure indicators.
7. Advances in technologies applicable to exposure science and the interconnection of open access (big) data domains provide new opportunities for exposure research, monitoring and assessment.
8. In Europe concerns and risks of CBRN threats are increasing raising the question whether and how current methods and tools that are driven by safety can accommodate security and vulnerability-driven exposure and risk assessment.
9. Beneficial to integrate human health and the environment data (one health cloud) for streamlining assessments in regulations cross-cutting health and environment.
10. Creating mechanisms to combine development and application of different models and data across various domains and regulations.
11. ISES Europe could serve as a platform that provides expertise to create a suite of educational resources in exposure science from short introductory style courses to PhD level exposure science programmes.

Threats

1. Many gaps on exposure science exist, hampering progress towards a sustainable development, including (a) overall exposure of humans and the environment to chemicals (in particular mixtures) and UVCB substances, (b) information on the use of chemicals (in products and articles) and the overall load of chemicals to the environment and to the technosphere, (c) failing regulatory implementation of environmental and human biomonitoring advances in the EU, and (d) estimation of releases from materials and articles, and proper quantification of low exposure levels.
2. Expectations arising from the development of ISES Europe cannot be met because of inadequate resources and/or the lack of availability of necessary expertise.
3. Assessments for regulatory purposes – like REACH - may become even more focussed on hazard alone.
4. Access to exposure studies may become even more limited because of commercial/confidential issues.
5. Dependence on black box tools may increase with the growth of artificial intelligence.
6. Harmonisation across the various disciplines that rely on exposure science may be strongly resisted or biased/political interpretation of exposure data may discredit exposure science.
7. Poor quality data/publications may undermine confidence in exposure science.
8. 'Silo' mentality between scientific disciplines and insufficient collaboration between disciplines and stakeholders.

3.3 Needs Assessment

The SWOT analyses and discussions during the workshop related to the identification of key needs and building blocks of a European Exposure Science Strategy. The generic key needs identified across the six identified thematic areas are:

1) Identity: Defining the field of exposure science and finding an identity as exposure scientists;

2) Communication: establishing a long-term dialogue between disciplines within and outside exposure science;

3) Tools: Organization of tools, standardization, harmonization across disciplines within and linked to exposure science.

As a result, the key building blocks should cover the following four exposure science domains and focus particularly on the following issues:

- Legislation and regulation regarding exposure assessment, material, facilities and activities:
    - Data storage

  - Standardisation and harmonisation where possible
  - Common framework for exposure science across regulatory schemes
  - Creation of incentives for sharing data and models
  - Respecting privacy, anonymity and intellectual property rights
- Exposure management tools, guidance, procedures and authorities
  - Transparency, reliability and uncertainty in regulatory exposure assessments
  - Coordination between and in-between stakeholders and EU and national agencies
  - Organisation of resources and development of business model to ensure sustainability and prevent collapse in case of resources unavailability
  - Better use and communication of the societal benefits of exposure science
  - Ensure a holistic approach comprising all types of exposure related aspects including social aspects, occupational, consumer and environmental exposures
  - Proper assessment of what is already available (no development of new instruments/tools before checking the applicability and suitability of what already exists)
- Assessment, detection, monitoring of exposure
  - Consolidated and robust methods to assess aggregate and combined (mixture) exposure
  - Methods to estimate releases from materials and products
- Collaboration, education and training
  - Creation of identity for exposure science as a scientific discipline which will deliver "exposure scientists" also in terms of a career pathway
  - Development of certified training and education establish exposure science as a professional discipline
  - Building strong alliances
  - Transparency in operating procedures and enhanced communication with relevant stakeholders

3.4 Established Building Blocks, Actions and Project Development

After having identified needs and potential options, the participants discussed the required actions and building blocks to be conducted after the workshop.

The following tables summarise the proposed building blocks, actions and ideas for project development for each of the six breakout groups.

Data repositories and analytics

A data repository is known as a data library or data archive that collect, manage, and store data sets for data analysis. The breakout group "Data repositories and analytics" considered that a virtual exposure platform would support the harmonisation of exposure assessments and help standardise data collection methods and procedures. Five possible working groups were identified each having a specific focus aiming at a better and more comparable use of models and data. The building blocks, actions and potential projects are listed in Table 1.

Table 1. Proposed building blocks, actions and ideas for project development related to data repositories and analytics.

Building blocks	Actions	Project development
Platform/portal	Establish a portal with: a) Standardised model for data collection b) Data quality assurance c) Meta templates documentation d) Controlled vocabularies	Inventory of portal needs
Working Groups	Setting up Working Group on Mapping	Mapping relevant models, data sources, exposure relevant determinants prioritising on harmonised/standardised/ widely used SOPs/templates in EU and beyond
	Setting up Working Group on Extending data use	Enable structured communication for each WG (Yammer, wiki, SharePoint, etc.) Memorandum of understanding between involved stakeholders; transparency; scope, recognition of ownership, rights and responsibilities
	Setting up Working Group on "Harmonisation"	Harmonisation (interoperability; control vocabularies, nomenclatures, data model and metadata templates
	Setting up Working Group on "Interoperability"	Data sharing principles/data provision incentives IT technologies, distributed systems, platforms
	Setting up Working Group on "Quality Assurance"	Setting up QC/QA procedures

Regulatory exposure assessment

Exposure assessment is subject to regulatory requirements that are defined by each sort and area of regulation. Although the end result may be similar, like it is safe, or not safe, or it poses a risk, or the risk is acceptable, the way how to come to the result commonly differs. Amongst other factors, this depends on differences in terminology throughout EU policies and on the use and documentation of data and models. The breakout group "Regulatory exposure assessment" considered that the establishment of a common framework focusing on efficiency enhancement across policies using exposure sciences is key. This framework should characterize the needs in exposure science across regulations and promote harmonisation of terms, vocabulary, templates for model documentation throughout the EU -legislation. Furthermore, three working groups were identified, each of which has a specific focus with regard to assessment method aspects and communication. The building blocks, actions and potential projects are listed in Table 2.

Table 2. Proposed building blocks, actions and ideas for project development related to regulatory exposure assessment.

Building blocks	Actions	Project development
Common framework of regulatory exposure assessment science across the different regulatory frameworks with relevant exposure evaluation	Organisation of common framework focusing on efficiency enhancement across policies using exposure sciences	Harmonisation of terms and vocabulary throughout EU-legislation (ISES to provide starting point for implementation in existing legislation) Harmonised template for model documentation and reporting; Common framework for model acceptance Characterisation of differences in exposure science needs across regulations Harmonisation of models across and within regulations Development of a more common understanding how safety assessment under REACH and work place risk assessment/management under OSH could work together
Working Groups	Setting up Working Groups on "transparency/ reliability/ uncertainty"	Rules and guidance for uncertainty analysis and examples how to address uncertainties in decision making Criteria or scoring system for reliability of measured and modelled data Transparency in assessments to better share knowledge and methods Read-across of available data Guidance to identify and describe contextual information for exposure information and data (e.g. measurement method, use information, duration …)
	Setting up Working Group on "Model development"*	Further develop models/methods for mixtures, release from articles and aggregate exposure Ensure development of tools until their regulatory readiness, including validation, user-interface and transparent documentation

		Develop guidance on what tool/model to use in different situations ensuring the complexity for being used in regulatory context is at acceptable level Setting up a business model ensuring long-term maintenance of models
	Setting up Working Group on "Communication"	Acceptance of risk levels based on quantitative exposure data Improvements in supply chain communication on uses, use-conditions and related exposure Improving exposure scenarios beyond use descriptors resulting in higher usefulness for practical risk management Influence the EU-framework project agenda Regulatory harmonisation and acceptance Success stories and 30 seconds messages Establish communication channels between different stakeholders (industry, decision-makers, grant holders, academic, risk assessors and disseminators)

*also suggested by breakout group "Exposure assessment and tools"

Building partnerships and collaboration

Forming partnerships and relationships with other stakeholders dealing with exposure science can be vital to the success of each stakeholder. Success can be measured or expressed in different ways including efficiency enhancement, cost saving, shared burden, etc. In order to achieve success, stakeholders must be open to collaborate and share not only within their own institute or company, but also between institutions and companies. The breakout group "Building partnerships and collaboration" identified the building of European Partnerships as key. These partnerships will promote the creation and development of European networks in Exposure science enhancing multidisciplinary collaboration promoting synergies between scientists from different disciplines, policy-makers, practitioners and citizens. These networks will exchange information relevant for the development, identification, promotion and exchange of best practices, education and training, and raising awareness of the added value of exposure science. One working group was identified that could support the building of European networks. The building blocks, actions and potential projects are listed in Table 3.

Table 3. Proposed building blocks, actions and ideas for project development related to building partnerships and collaboration.

Building blocks	Actions	Project development
European networks	Building Partnerships to promote the creation and development of European networks and related activities in Exposure science	Networking among key stakeholders and key groups/projects, like HEAdhoc, REEG groups, and HBM4EU Development, identification, promotion and exchange of best practices Provide technical and capacity development support to each other Preparation, development and implementation of education and training modules and tools aiming to increase multidisciplinary collaboration Raising awareness of the added value of exposure science Promoting synergies between science, health, regulator, consumers
Working Group	Setting up Working Group on "Partnerships"	Making inventory of stakeholders from the Workshop's participants Making inventory of individuals who can provide links to stakeholders (e.g., people with current memberships of other societies) Creation of success stories representing who we are and what we can offer (guidelines, best practices, movies), featuring different success stories for different stakeholders

Exposure data production and monitoring

Exposure data production and monitoring is very important not only to comply with regulations, but moreover to provide safety and security to workers, consumers and the environment. Exposure data production is essential for exposure management that aims at the elimination of hazardous sources, at improvement of the production processes and products. This is made possible (among others) by data production and monitoring. Data production and monitoring (and collection) allows for the analysis of the potentially exposure-related causes of various phenomena in any period of time, current exposure assessment and forecasting future exposures. The breakout group "Exposure data production and monitoring" identified the creation of a handbook of best practices as key to covering all aspects of exposure science including exposure scenarios, the collection of standardization and harmonization efforts and a quality rating tool for data and models. One working group or a project was proposed regarding a database for exposure factors in Europe. The identified building blocks, actions and potential projects are listed in Table 4.

Table 4. Proposed building blocks, actions and ideas for project development related to exposure data production and monitoring.

Building blocks	Actions	Project development
Handbook of best practice	The long-term aim would be to develop of a handbook of best practices covering all aspects of exposure science including data production and monitoring. For this purpose, a Working Group on "Common standards in safety and security-driven exposure data production and monitoring" may be established.	Start with mapping what is there Separate by exposure science related fields, collect standards/harmonisation efforts in these fields Define which contextual information should be available in connection with samples Develop quality rating scheme (Q-factors like in ConsExpo fact sheets?)
Working Group	A working group or a project on "A data base for exposure factors in Europe" (building on national handbooks, JRC ExpoFacts or ConsExpo Fact sheets)	Revitalisation of European exposure factor collection including a. Definition of needs, hosting and quality requirements b. Use of existing formats, like ConsExpo fact sheets or OECD harmonised template OHT301 c. Setting up a Committee that derives standard default values in specific areas d. Preparation of and requesting funding for a COST action project

Exposure assessment methods and tools

Exposure assessment methods and tools largely drive the outcome of exposure assessment. One could use good data, but apply an inappropriate method and produce an inaccurate exposure assessment. Furthermore, a method that is adequate to use for one regulatory purpose may not necessarily be an appropriate method to be used within the frame of a different regulatory framework. The breakout group "Exposure assessment methods and tools" identified the establishment of integrated frameworks for the assessment of multiple (aggregate, cumulative, mixture) exposures as key. Integrated frameworks should function on the basis of multi-tier tools and models can constitute the starting point for building a common exposure science framework across policy domains based on harmonising and building consistency in used data and models. One working group was identified that could establish the landscape regarding user information. The building blocks, actions and potential projects are listed in Table 5.

Table 5. Proposed building blocks, actions and ideas for project development related to exposure assessment methods and tools.

Building block	Actions	Project development
Integrated framework(s)	Develop integrated frameworks for exposure assessment	Map multiple different stressors (chemical mixtures) and over the different regulatory domains (aggregate exposure) Evaluate REFIT effort results Creating consistent integrated multi-tier tools Identify main contributors (e.g. associations) Define common exposure aspects across regulations Develop/align methods with emerging toxicity data and models (e.g. in-vitro testing) Establish linkages with common framework of regulatory exposure assessment science and the development of the IT platform/portal
Working Groups	Setting up Working Group on "User information"	Inventory existing information tools/templates Identify user needs across domains Harmonisation of vocabulary/results reports Define limits, scope, applicability domain, etc. across available methods and tools Build common, consistent structures to inform users about exposure methods and tools
	Setting up Working Group on "Model evaluation"*	Identification of (applicability) gaps and inform on needs for new data generation Develop methods for evaluation of models Define uncertainty factors for default values

*also suggested by breakout group "Regulatory exposure assessment"

Exposure education and communication

In the past, exposure assessments were typically only concerned with external exposure to chemicals. Today, the concept of what is embraced by exposure assessment has changed. It is now recognised that:

- it is the internal exposure that should be the connection between toxicology and exposure assessment. This implies the examination of toxicokinetics and absorption processes;
- Exposure science should embrace exposure to non-chemical stressors (biological and physical);
- Exposure to combinations of stressors requires much greater emphasis.

This recognition emphasizes the need for an initiative to develop postgraduate exposure science training in order to address the lack of sufficient expertise in exposure assessment. In the past, risk assessments often only gave limited attention to exposure assessment but, with a growing interest in health screening, and ever-increasing domains for which risk assessments are required, a new risk assessment paradigm, centred on exposure assessment has become vital. The breakout group "Exposure education and communication" proposed that ISES Europe should take up the role of communicator and trainer supporting the development of a tiered education/training scheme with ECTS equivalent points/credits. One working group was identified that should explore possibilities along these lines. The building blocks, actions and potential projects are listed in Table 6.

Table 6. Proposed building blocks, actions and ideas for project development related to exposure education and communication

Building block	Actions	Project development
Foundation of ISES Europe as a communicator and trainer.	Develop a certified tiered ISES Europe approach to ES education with ECTS (European Credit Transfer System) equivalent points/credits	Description of type of course (Short term – online course, Intermediate term – specialised workshops, Long term goal – postgraduate course) Identify possible cost actions to fund course/programme development and delivery Identify potential sources of funding from industry
Working Group	Setting up Working Group on Working Group/Advisory panel on "Exposure Science Education, Training and Communication"	Propose short courses during conferences (e.g. SETAC pre-conference 1-day short courses) Seek participation from all relevant stakeholders including representatives of ISES Europe, Industry, Policy-makers, Academia, Insurers, and other Professional Societies Provide a list of the identified academic programmes on the ISES Europe website (informative – not accredited). Explore potential role of ISES as a training course approver or accrediting body Define EES career paths that reflect career options within each stakeholder group, publish on the ISES website Creation of a Syllabus on Exposure Science understand stakeholder needs and requirements for education/training

		Identify academic programmes with ES components and check the guidelines (ECTS) for credit requirements Liaise/collaborate with professional/scientific societies representing related professions (e.g. BOHS, SETAC, EUROTOX)

4 Discussion and Conclusions

In the last ten years, the societal and political environment in Europe with respect to environmental pressures and risks related to safety and security threats, such as CBRN materials[1], physical phenomena, but also psychological and social phenomena, have changed. These changes, together with EU strategies aiming at a safe, secure, non-toxic and sustainable society trigger the need to provide reliable exposure information. On the June 19-20, 2018, 119 scientists from nine societal stakeholder groups comprising the European Commission, European agencies, national authorities, industry, academia, consultants and insurers, met together during a workshop organized by the ISES Europe. Efforts were joint to develop a *European Strategy for Exposure Science* with a roadmap 2020-2030, starting by defining the foundation for such a strategy. Key needs, building blocks, actions and ideas for projects were identified along six thematic areas that are relevant for exposure science, including 1) data repositories and analytics, 2) regulatory exposure assessment, 3) exposure data production and monitoring, 4) building partnerships and collaboration, 5) exposure assessment methods and tools and 6) exposure education and communication.

It was concluded that the following building blocks and actions are needed as a foundation of a European Exposure Science Strategy:

1. **Establishment of a common web portal**: to be used as a virtual exposure platform to help harmonizing exposure assessments and standardizing data collection methods and procedures.

2. **Establishment of a common framework focusing on efficiency enhancement across policies relying on exposure sciences**: The common framework of regulatory exposure assessment science across the different regulatory frameworks should characterize the needs in exposure science across regulations and promote harmonisation of terms, vocabulary, templates for data and model documentation throughout the EU legislation.

3. **Establishment of European networks**: Building European partnerships that promote the creation and development of European networks in Exposure science should enhance multidisciplinary collaboration promoting synergies between scientists from different disciplines, policy-makers, practitioners and citizens. These networks are envisaged to exchange information relevant for the development, identification, promotion and exchange of best practices, education and training, and raising awareness of the added value of exposure science.

4. **Establishment of integrated exposure assessment framework(s):** Integrated frameworks for the assessment of multiple (aggregate, cumulative, mixture) exposures that function on the basis of multi-tier tools and models can constitute the starting point for building a common exposure science framework across policy domains based on harmonising and building consistency in used data and models.

5. **Development of a Handbook of Best Practices**: the development of a handbook of best practices covering all aspects of exposure science including exposure scenarios, the collection of standardization and harmonization efforts and a quality rating tool for data and models in use.

[1] See also latest report and concluding remarks by EU President Donald Tusk to the European Parliament on October European Council meetings, Speech 596/18, 24.10.2018, https://www.consilium.europa.eu/en/press/press-releases/2018/10/24/report-by-president-donald-tusk-to-the-european-parliament-on-october-european-council-meetings/pdf.

6. **Establish ISES Europe as a communicator and trainer**: via the development of a tiered education/training scheme with ECTS equivalent points/credits.

To realize these building blocks and actions, a community of practise for European exposure science will be created that will consist of specific working groups. ISES Europe will take the role of a facilitator for these working groups, each of which will have the task to further elaborate the project development ideas and to explore funding possibilities enhancing collaboration and the exchange of knowledge amongst and between stakeholders. Proposals of working groups can be submitted to the ISES Europe board.

This report is the first step in the process of building a European strategy for exposure science, and the authors of this report agree on the approach and content.

ISES Europe seeks to organize its second meeting in 2019 during which representatives of the community of practise and members of the working groups will be called to develop a concrete action plan consisting of the prioritized actions and project development according to respective timelines. The results of the action plan will shape the *European Strategy for Exposure Science* with a roadmap 2020-2030.

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List of abbreviations and definitions

BAuA	German Federal Institute for Occupational Safety and Health
CBRN	Chemical, Biological, Radiological and Nuclear
BOHS	British Occupational Hygiene Society
COST	European Cooperation in Science and Technology
ECTS	European Credit Transfer System
EU	European Union
ES	Exposure Scenario or Exposure Science
ETF	European Training Foundation
Exposure Science	The science of the contact between stressors (primarily chemical, biological, and physical agents) and receptors (e.g. molecules, cells, organs, humans, other living organisms, and non-living items like buildings), and the associated pathways and processes potentially leading to negative effects on human health and the natural and built environment
HBM4EU	European Human Biomonitoring Initiative
HEAdhoc	Ad hoc Working Group on Human Exposure (Biocides)
IPCheM	Information Platform for Chemical Monitoring
ISES Europe	International Society of Exposure Science Europe
JRC	Joint Research Centre of the European Commission
OECD	Organisation for Economic Co-operation and Development
OHT	OECD Harmonised Templates
QC/QA	Quality Control/Quality Assurance
REACH	Registration, Evaluation, Authorisation of Chemicals, Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
REEG	Reach Exposure Expert Group
REFIT	The European Commission's regulatory fitness and performance programme
SETAC	Society of Environmental Toxicology and Chemistry
SME	Small and Medium Enterprises
SOP	Standard Operating Procedure
SWOT	Strengths, Weaknesses, Opportunities and Threats
UVCB	Chemical Substances of Unknown or Variable composition, Complex reaction products or Biological materials

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Appendix A: Workshop Agenda

DAY 1: Tuesday, 19-June-2018

Exposure Science in Europe - Topics, needs, and questions			
08:00-08:30	Registration		
08:30-08:45	Welcome Lecture Hall Rolf Packoff, Head of Scientific Management, German Federal Institute for Occupational Safety and Health		
08:45-09:00	Introduction to 1st ISES-Europe Workshop Lecture Hall Yuri Bruinen de Bruin, President of ISES-Europe, European Commission Joint Research Center		
09:00-09:30	Keynote lecture: Scientific Visions for European Exposure Science Lecture Hall Roel Vermeulen, Professor, Institute for Risk Assessment Sciences - Environmental Epidemiology, Utrecht University		
09:30-10:00	Keynote lecture: Visions for Regulation and Implementation of European Exposure Science Lecture Hall Peter Korytar, Policy Officer at the European Commission, Directorate General Environment		
10:00-10:30	Q&A and formation of break-out working groups Lecture Hall Alison Connolly, ISES-Europe Student Representative; Peter Fantke, ISES-Europe European Exposure Science Strategy		
10:30-11:00	Coffee and Poster viewing (odd poster IDs; please stand by your poster)		
11:00-13:00	Break-out session: Data Repositories & Analytics Introduction [15 min] Framing of questions [15 min] Discussion [60 min] Preparation of summary presentation [30 min] Room 502	Break-out session: Regulatory Exposure Assessment Science Introduction [15 min] Framing of questions [15 min] Discussion [60 min] Preparation of summary presentation [30 min] Room S11	Break-out session: Building Partnerships & Collaboration Introduction [15 min] Framing of questions [15 min] Discussion [60 min] Preparation of summary presentation [30 min] Room E08
13:00-14:00	Lunch and Posters (odd poster IDs; please stand by your poster)		
14:00-16:00	Break-out session: Exposure Data Production & Monitoring Introduction [15 min] Framing of questions [15 min] Discussion [60 min] Preparation of summary presentation [30 min] Room 502	Break-out session: Exposure Assessment Methods & Tools Introduction [15 min] Framing of questions [15 min] Discussion [60 min] Preparation of summary presentation [30 min] Room S11	Break-out session: Exposure Science Education, Training & Communication Introduction [15 min] Framing of questions [15 min] Discussion [60 min] Preparation of summary presentation [30 min] Room E08
16:00-16:30	Coffee and Posters (odd poster IDs; please stand by your poster)		
16:30-17:00	Poster Pitches (pre-selected poster IDs only) Lecture Hall Chair: Jos Bessems, ISES-Europe Secretary/Treasurer		
17:00-18:00	Day 1 wrap-up presentations and agreement on discussions for Day 2 Lecture Hall Chair: Natalie von Goetz, ISES-Europe Outreach & Education		
18:00-19:00	Guided tour through DASA Working World Exhibition (5 min. walk from workshop facilities)		

19:00-22:00	BAuA/ISES-Europe Dinner at DASA Working World Exhibition, Room: "Stahlhalle" (all workshop participants are invited)

DAY 2: Wednesday, 20-June-2018

Exposure Science in Europe - From theory into practice and future research agenda

08:30-09:00	Exposure Science, Building a Strategy for Europe Lecture Hall Yuri Bruinen de Bruin, President of ISES-Europe, European Commission Joint Research Center		
09:00-09:20	Keynote lecture: Implementing Exposure Science in Practice of Risk Assessment Lecture Hall Tim Meijster, Health and Safety Risk Management, Innovative technologies, Shell/ECETOC		
09:20-09:40	Keynote lecture: Implementing a Strategy for Exposure Science in Practice Lecture Hall Jim Bridges, Emeritus Professor, Toxicology & Environmental Health		
09:40-10:00	Q&A and plenary discussion on ways toward a European Exposure Science Strategy Lecture Hall Peter Fantke, ISES-Europe Councillor European Strategy on Exposure Science		
10:00-10:30	Coffee and Posters (even poster IDs; please stand by your poster)		
10:30-11:30	Break-out session: Data Repositories & Analytics Framing of questions [10 min] Discussion [30 min] Preparation of summary presentation [20 min] Room 502	Break-out session: Regulatory Exposure Assessment Science Framing of questions [10 min] Discussion [30 min] Preparation of summary presentation [20 min] Room S11	Break-out session: Building Partnerships & Collaboration Framing of questions [10 min] Discussion [30 min] Preparation of summary presentation [20 min] Room E08
11:30-12:30	Break-out session: Exposure Data Production & Monitoring Framing of questions [10 min] Discussion [30 min] Preparation of summary presentation [20 min] Room 502	Break-out session: Exposure Assessment Methods & Tools Framing of questions [10 min] Discussion [30 min] Preparation of summary presentation [20 min] Room S11	Break-out session: Exposure Science Education, Training & Communication Framing of questions [10 min] Discussion [30 min] Preparation of summary presentation [20 min] Room E08
12:30-13:30	Lunch and Posters (even poster IDs; please stand by your poster)		
13:30-14:00	Poster Pitches (pre-selected poster IDs only) Lecture Hall Chair: Natalie von Goetz, ISES-Europe Outreach & Education		
14:00-15:00	Day 2 wrap-up presentations Lecture Hall Chair: Jos Bessems, ISES-Europe Secretary/Treasurer		
15:00-15:30	Plenary discussion on European Exposure Science Strategy next steps Lecture Hall Peter Fantke, ISES-Europe Councillor European Strategy on Exposure Science		

15:30-16:00	Workshop wrap-up and closure Lecture Hall Yuri Bruinen de Bruin, President of ISES-Europe, European Commission Joint Research Center
16:00	Coffee and Departure

Appendix B: List of participants' affiliations

ACES, Stockholm University
AMD TÜV Arbeitsmedizinische Dienste GmbH
ANSES
BASF SE
Berufsgenossenschaft für Gesundheitsdienst und Wohlfahrtspflege (BGW)
Biesterfeld ChemLogS GmbH
Bundesamt für Gesundheit (BAG) Schweiz
Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA)
Bundesinsitut für Risikobewertung (BfR)
C.S.B. GmbH
CARL BECHEM GMBH
Centre for Climate Change & Air Pollution Studies & Ryan
Chemservice S.A.
Clariant Produkte (DE) GmbH
Cosanta BV
Creme Global
Dr. Knoell Consult
DyStar Colours Distribution GmbH
EBRC Consulting
EC Joint Research Centre
ECHA
EFSA
EHESP
EHESP/Irset
EQUITOX
ERM GmbH
Escola Superior de Tenologia da Saúde de Lisboa
eupoc GmbH
Eurometaux
European Commission, DG Environment
European Commission, Joint Research Centre (JRC)
Exxon Mobil
FEICA
FoBiG
Fraunhofer Instiute for Toxicology and Experimental Medicine (ITEM)
Fraunhofer-Institut für Biomedizinische Technik (IBMT)
French Agency for Food, environmental and occupational health & safety (ANSES)
GEELIO Umwelttechnologie GmbH

Health and Safety Executive
IFA of the DGUV
INERIS
Institut für Energie- und Umwelttechnik - IUTA e.V.
Institut für Prävention und Arbeitsmedizin (IPA)
Institute for Prevention and Occupational Medicine of the German Social Accident Insurance (IPA)
Institute of Occupational Medicine
International Cadmium Association
ISGlobal
KIST Europe
L´Oreal
Labour Inspectorate
National Institute for Public Health and the Environment
National University of Ireland, Galway (NUI Galway)
PFA-Brussels
RIVM
Sasol Germany GmbH
SECO
Shell
Sika Technology AG
Technical University of Denmark
THL Public Health Solutions
TNO
Toxicology and Environmental Health
Umweltbundesamt, Germany
Umweltbundesamt GmbH, Austria
Utrecht University
VECCO e.V.
VITO Health
Zschimmer & Schwarz GmbH & Co KG

Appendix C: Session chairs, co-chairs, rapporteurs and moderators

Data Repositories and Analytics Tuesday 11:00-13:00 / Wednesday 10:30-11:30

Chair	Stylianos Kephalopoulos (Coordinator of IPCHEM, European Commission, Joint Research Centre, Italy)
Co-Chair	Tanya Dudzina (Exposure Scientist, ExxonMobil, Belgium)
Rapporteur	Otto Hänninen (Senior Researcher, THL Public Health Solutions, Kuopio/Finland)
Moderator	Jos Bessems (Senior Researcher, VITO - Flemish Institute for Technological Research, Belgium)

Regulatory Exposure Assessment Science Tuesday 11:00-13:00 / Wednesday 10:30-11:30

Chair	Theo Vermeire (Dutch National Institute for Public Health and the Environment (RIVM), Chair of SCHEER, The Netherlands)
Co-Chair	Andreas Ahrens (Directorate C – Registration, European Chemicals Agency, Finland)
Rapporteur	Tim Meijster (Health and Safety Risk Management, Innovative technologies, Shell/ECETOC, Belgium)
Moderator	Urs Schlüter (Head of Unit Federal Institute for Occupational Safety and Health, BAuA, Germany)

Building Partnerships & Collaboration Tuesday 11:00-13:00 / Wednesday 10:30-11:30

Chair	Jim Bridges (Emeritus Professor, University of Surrey, and Research for Sustainability, Guildford UK)
Co-Chair	Jelle Vlaanderen (Asst. Professor, Institute for Risk Assessment Sciences, Utrecht University, The Netherlands)
Rapporteur	Maryam Zare Jeddi (Researcher, Division of Toxicology, Wageningen University and Research, The Netherlands)
Moderator	Yuri Bruinen de Bruin (European Commission Joint Research Centre, Italy)

Exposure Data Production & Monitoring Tuesday 14:00-16:00 / Wednesday 11:30-12:30

Chair	Michael McLachlan (Professor, University Stockholm, Sweden)
Co-Chair	André Conrad (Senior Researcher, German Environment Agency, Germany)
Rapporteur	Susana Viegas (Associate Professor, Escola Superior de Tecnologia da Saúde de Lisboa, ESTeSL-IPL, Portugal)
Moderator	Natalie von Goetz (Senior Researcher, Federal Office of Public Health, Switzerland)

Exposure Assessment Methods & Tools Tuesday 14:00-16:00 / Wednesday 11:30-12:30

Chair	Claudia Cascio (Scientific Officer, European Food Safety Authority, Italy)
Co-Chair	Amélie Crépet (Scientific project manager, French Agency for Health and Safety; France)
Rapporteur	Dag Rother (Senior Researcher, Federal Institute for Occupational Safety and Health, BAuA, Germany)
Moderator	Peter Fantke (Associate Professor, Quantitative Sustainability Assessment, Technical University of Denmark)

Exposure Science Education, Training & Communication Tuesday 14:00-16:00 / Wednesday 11:30-12:30

Chair	Marie Coggins (Academic Director MSc OESH, National University of Ireland, Ireland)
Co-Chair	Gerhard Heinemeyer (Former Head of Unit, German Federal Institute for Risk Assessment, Germany)
Rapporteur	Véronique Poulsen (Head of Environmental Safety, L'Oréal, France)
Moderator	Alison Connolly (National University of Ireland, Ireland)

Appendix D: SWOT analyses results of the thematic breakout sessions

Table D1. Data Repositories and Analytics

Strengths	Weaknesses	Opportunities	Threats	Needs	Building blocks
Well-developed approaches in various fields such as food contamination IPCHEM, marine monitoring, waste directive/recycling, chemicals legislation Harmonized monitoring obligations Templates (ECHA) High quality data, good laboratory practices Interoperability multidisciplinary collaboration EBD studies (e.g. smoking) INSPIRE Directive: interoperable format Integrated analysis Comparative risk assessment, prioritization (e.g. EBD approaches) Existing data would be more available if tools would allow for sharing sensitive data as anonymised or pseudonymised data Measured data supports modelling	Data is often not published or made available beyond original use Need of contextual information Field silos Divided dBs, multidisciplinary Lack of common understanding of vocabulary Sharing raw data (vs aggregate data) Unclear agenda/objectives Sectorial approaches, need for harmonization/standardization Unknown exposure relevance Regulated vs unregulated risks	Full picture of exposures Cross evaluation, Quality Assurance, standardization Data citation index Additional value in data collected (not only compliance)(use both for models and data analysis) Comparison of data from multiple methods/angles (e.g. models vs. measurements) Public money=public of data Automation (IHME GBD model) Publication and sharing credits approaches Model development Identification of main determinants Big data on exposures, health Multiple exposure comparison, risk prioritization Aggregate anonymous analysis Scenario assessment, method harmonization (using metadata) Company name hiding Moving from mechanistic models towards more ad hoc data analysis	Privacy, security, integrity, QA Intellectual property rights Lack of documentation, common vocabulary, contextual information Conflicting analysis of same data (threat or strength? cf. cross validation) Lack of analytical models for big data (cf. Exposome) Data updates, maintenance Privacy Misinterpretations Misuse by interest groups Industries at risk Data quality needs; lack of documentation Speed of data becoming available	Data storage Management of distributed systems Coordination (of the well-developed approaches, methods) Sharing model, QA Publication and crediting approaches Sustainable governance scheme and funding IT tools to guarantee data privacy/IPR security	Platform/portal Working Groups Project development

Table D2. Regulatory Exposure Assessment Science

Strengths	Weaknesses	Opportunities	Threats	Needs	Building blocks
Many regulatory frameworks (REACH, Biocides, Plant Protection, ROHS, construction materials, food contact materials, medical devices, Occupational Health and Safety …) take exposure assessment information into account for risk assessment and decision making. A systematic use and combination of this information should make it possible to create a full description (total exposure, i.e. a combination of all substances and sources across regulations and over time) of human and environmental exposure to chemicals. In this context, REACH is meant to close the gaps for chemicals or for certain life-cycle stages for which no specific framework exists.	For a number of "situations" exposure assessment methods are missing in current regulatory frameworks, although large variations exist between frameworks: • Mixtures • Low Exposure Levels (Models & Monitoring) • Approaches to address uncertainty beyond simply applying conservatism • Estimation of releases from materials and articles • Aggregate exposure assessment (routes/sources and substances) For exposure assessments in regulatory frameworks no incentives and mechanisms are implemented to motivate for data sharing (e.g. use, exposure, release information) across these frameworks. Although in REACH a lot of exposure data is collected in consortia, little of this data is publicly available. There is also no clear agreement on what data should be prioritized, and practical implementation is missing regarding for sharing exposure information up and down the supply chain. Weight of evidence approaches are not implemented in regulatory exposure assessment systematically. This becomes particularly important when data from different sources or across different regulatory frameworks, with different quality will be combined in risk assessment. Aggregate exposure estimation (total exposure to a substance from different	A higher profile for exposure and use information would allow for more risk-based regulation and risk management in different regulatory frameworks. A common framework across regulations will stimulate data and methodology sharing as well as transparency.	Wrong decision making due to • "Misuse" of exposure data or • Lack of quality of exposure data (exposure again means use, release, exposure). Inefficiency of exposure assessments.	Common framework for exposure science across regulatory schemes (in random order) • Harmonisation of terms and vocabulary throughout EU-legislation (ISES to provide starting point for implementation in existing legislation) • Harmonized template for model documentation and reporting; Common framework for model acceptance • Characterization of differences in exposure science needs across regulations • Harmonization of models across and within regulations • Development of a more common understanding how safety assessment under REACH and work place risk assessment/management under OSH could work together. Transparency, reliability and uncertainty in regulatory exposure assessments (in random order) • Rules and guidance for uncertainty analysis and examples how to address uncertainties in decision making • Criteria or scoring system for reliability of measured and modelled data • Transparency in assessments for sharing • Read-across of available data	Based on the needs, two key building blocks were identified that could be dealt with in working groups: • Common framework of regulatory exposure assessment science across the different regulatory frameworks with relevant exposure evaluation • Harmonised/common understanding of dealing with reliability and uncertainty respectively in regulatory exposure assessments Additionally, the identified needs and goals regarding tools and communication indicate that a detailed exchange

Strengths	Weaknesses	Opportunities	Threats	Needs	Building blocks
	sources) as foreseen in several regulatory frameworks but not implemented in standard assessments is considered a challenge. So far no harmonised, integrated approach is available for exposure science/assessment as there is no common understanding of exposure science across different regulatory frameworks, stakeholders or disciplines.			• Guidance to identify and describe contextual information Model development (in random order) • Further develop o models/methods for mixtures, o release from articles and o aggregate exposure; • Ensure development of tools until their regulatory readiness, including validation, user-interface and transparent documentation; • Ensure that models do not get too complex for being used in regulatory context; • Develop guidance on what tool/model to use in different situations • Put business model in place ensuring long-term maintenance. Communication (in random order) • Acceptance of risk levels based on quantitative exposure data • Improvements in supply chain communication on uses, use-conditions and related exposure • Improving exposure scenarios beyond use descriptors resulting in higher usefulness for practical risk management • Influence EU-framework project agenda • Regulatory harmonization and acceptance	with other working groups within ISES Europe is obligatory: • Exposure science methods and tools; dealt with in session 5 Exposure science education, training and communication

Table D3. Building Partnerships and Collaboration

Strengths	Weaknesses	Opportunities	Threats	Needs	Building blocks
Common focal point on exposure issues for both companies and decision-makers Harmonization of sampling, measurements, statistics exposure assessment models Ability to integrate/ensure collaboration between relevant sub-disciplines Learn from other fields Consistent outputs and trust building supporting acceptance, good communication channels One contact point for EU exposure science Breadth of expertise spanned by ISES Europe	Data protection regulation obstacles Problems of existing Data diversity/Diversity of exposure modelling/ methodology sharing Definition and goals of collaboration/ where can we collaborate? Major gap between occupational risk assessment and environmental risk assessment Unawareness on secondary exposure via environment Lack of considering human behaviour in developing risk communication skills Absence of using media to cross the common message of scientist and regulators to public Environmental and public health/Health care are the missing parties Insufficient information about existing professional societies and learning from them Research ethics is a missing area Problems of whether to fit ISES Europe role around legislation or start with what is scientifically optimal Large variation in data bases (content and validity)	Save money, more effective collaboration, more data available Addressing key current exposure issues, better possibilities to influence regulators and funders Involving industry, working with others, Communicating according to regulator and company perspectives, more ability to pick up and comply with regulation Beneficial to an integrated approach for human and environmental health	Socio-economic is not involved Problems of data sharing/ownership among stakeholders Missing common language/terminology among regulations Insufficient data on non-chemical stressors Insufficient collaboration among academic, regulators, industries and other related stockholders in an open manner To update needs and current developments/ shortage of experts who are available Translate the scientific knowledge in a comprehensive/ understandable way for regulators and other stakeholders Lacking link between different scientific disciplines to solve the conflict between toxicologists and exposure scientists	Establishment of exposure science as a recognized scientific discipline and communications with all relevant stakeholders Strong alliances, trust, transparency, loyalty Use recommendations from national surveys to better include public health/exposure aspects Translate exposure science into societal benefits Ensure we capture all exposures, holistic approach to exposure science Connect monitoring from different micro environments for exposure science assessment Common objectives for exposure research Connecting pathways, tap into public services e.g. water, air etc. and data bases Better use of what data is out there & how to more effectively communicate it Connection to other societies, insurances, companies, etc. Transparent objectives for stakeholders alignment to exposure strategy, need a statement outlining how their work aligns to exposure strategy	Partnerships Success stories Communication Regulations fitness check beyond chemicals

Table D4. Exposure Data Production and Monitoring

Strengths	Weaknesses	Opportunities	Threats	Needs	Building blocks
More data has become available (e.g., human/environmental biomonitoring, REACH, IPCHEM) Diversity in expertise	Data is lacking (e.g., dermal, product use/levels, exposure factors) Lack of contextual information Lack of standardisation in collection/reporting of data	Better archiving/communication of contextual data Diversity of experience in Europe Diversity of exposure scenarios in Europe Under exploited opportunities in studying interventions Portable monitoring & non-target analysis have future potential Linking to other European networks	Exposure data can become a risk for private insurance Unjustified extrapolation of data (in Europe) Funding	Handbook of best practice Ensuring contextual info is available Revitalization of European exposure factor collection Networking (across exposure science disciplines, regions)	Handbook of best practice Revitalization of European exposure factors collection Networking (across exposure science disciplines, regions)

Table D5. Exposure Assessment Methods and Tools

Strengths	Weaknesses	Opportunities	Threats	Needs	Building blocks
Exposure science community is already highly interdisciplinary Plenty of data and models already exist that we can learn from	Many models currently too complex to be used Often, model results not easily reproducible Models targeting the same question/issue are not harmonized Models often not well documented and not transparent Lack of connection between different exposure-related fields	Balancing model stability vs. state-of-the-art Increase open access of data (for data reuse) and open source of models to promote regulatory and stakeholder acceptance Creating a collaboration mechanism to combine different efforts in model development and application	Potential for misuse of models, particularly when open source Confidentiality issues/IPR can stand in the way for using models Missing mechanisms and funding for maintaining models and data	Easy to apply and user-friendly models Funding mechanisms required for including model documentation and implementation All models should include an appropriate level of uncertainty and state their assumptions Identification and prioritization of main contributors to overall exposure Model evaluation and where possible comparison against measurement data Integrated modelling frameworks to account for different exposure contexts (e.g. consumer, dietary, occupational, environmental)	User information Model evaluation Integrated frameworks

Table D6. Exposure Science Education, Training and Communication

Strengths	Weaknesses	Opportunities	Threats	Needs	Building blocks
Many courses/programmes available Lots of expertise Industry/regulatory agencies requires this expertise	Many disciplines do something with exposure science but there is poor communication between the disciplines – no holistic view Exposure scientists have uncommon backgrounds with different knowledge requirements Require cooperation with occupational, cosmetic and environmental exposure science	Examples of defined career pathways for Exposure Scientists exist within several employers (SME?) Previous programmes and societies that we can model our education programme Establish exposure science as a professional title Create holistic view on the Exposure Science career pathway	No common definition (not easy to define) Exposure Science has no identity Lack of funding Existing course – need to identify a requirement for a new course.	Development of a career pathway and curriculum on Exposure Science Allocation of funding resources Development of a tiered approach for education/ training Flexibility with courses so people can upscale their skills	Working Group/Advisory panel on Exposure Science Education, Training and Communication Clear defined career paths Making funding available (where and for what) Tiered ISES Europe education with ECTS equivalent points/certificates Identification of key stakeholders to understand needs and requirements for education/training ISES Europe as a communicator and educator/ trainer

Appendix E: List of Poster presented during the ISES Europe 2018 Workshop

Data Repositories and analytics

P1 Characteristics of 24-h Urine Samples and their Relevance for Human Biomonitoring - 20 Years of Trend Research

P2 Recent and on-going CEFIC Long Range Research Initiative projects to advance regulatory human exposure assessment for chemicals

P3 OCdBIO: a combined monitoring system to control Cd exposure at the workplace

P4 Possibilities and limitations of low cost PM sensors

P5 Applicability of optical aerosol spectrometers and photometers for the surveillance of workplace exposure concentrations

P6 DINCH Exposure in Germany has become omnipresent and is further increasing – urinary data from the German Environmental Specimen Bank (1999-2017)

Regulatory Exposure Assessment Science

P7 Chemicals Safety Assessment under REACH (1) – The exposure scenario concept, its challenges and solutions available

P8 Chemicals safety assessment under REACH (2) – Exposure modelling for improving the advice on safe handling and exposure controls in safety data sheets

P9 Estimating the release potential of additives from plastic articles – Method supporting prioritising and deprioritising of substances for further work

P10 Priorities in exposure assessment at RIVM

P11 REACh2SDS – Assessing the availability and quality of risk and risk management information in Chemical Safety Reports

P12 Quantifying the effectiveness of personal protective equipment against dermal exposure

P13 TRanslation of EXposure MOdels (TREXMO): Multi-model approach to assess occupational exposure to chemicals

P14 Overview of the EFSA Guidance on the assessment of exposure in risk assessment for plant protection products, Workshop 2018

P15 Biocidal pest control products - common exposure scenarios for professional users from the regulatory perspective

P16 Development of an integrated risk management measure library

Exposure Data Production & Monitoring

P17 Systematic analysis of dermal exposure to hazardous chemical agents at the workplace: outcome of the SysDEA project

P18 Exposure of Workers During Pest Control of the Oak Processionary Moth (OPM) by Spray Applications

P19 An exposure assessment study among amenity horticulturists using glyphosate based pesticide products

P20 Feasibility study for consumer behaviour data collection

P21 Lead Exposure of Young Adults in Germany – Long Time Experience of the German Environmental Specimen Bank (ESB)

P22 Elucidating Levels and Pathways of Human Exposure in Ireland to POP-BFRs and PFOS (ELEVATE)

P23 Estimating the early-life exposure to perfluorinated compounds using PBPK modeling and biomarker measurements

P24 The relevance of surfaces contamination monitoring for exposure assessment and control

Exposure Assessment Methods & Tools

P25 Assessment of the Oral Bioaccessibility of Semi-volatile Organic Compounds in Indoor Setteled Dust Using a Simplified Method

P26 MEASE 2 – Updated Occupational Exposure Assessment Tool for Metals and Inorganic Substances

P27 Exposure assessment combining air measurements and biomonitoring of systemic exposure is key to manage Cd risks at the workplace

P28 Development of a Job-Exposure Matrix for occupational exposure assessment of high frequency electromagnetic fields (3 kHz-300 GHz) in the INTEROCC study

P29 Exposure assessment of pregnant women to Di(2-ethylhexyl) phthalate by reverse dosimetry: Variability in repeated spot sample

P30 Deriving exposure limit values for electromagnetic fields

P31 The development of the mechanistic model underpinning the dermal Advanced REACH Tool (dART)

P32 SprayExpo - a deterministic indoor air model for spray applications

P33 Predicting exposure of humans to PCB 153 on a global scale

P34 A review of risk management measures & their impact on occupational exposure levels to hazardous substances

P35 Exposure Biomarker Candidates in Urine for the UV Filter Avobenzone

P36 Exposure to Phthalate Plasticizer Alternatives: Determination of DEHA Biomarkers in Human Urine

P37 Analysis of Specific Consumer Exposure Determinants (SCEDs) in comparison with observational data from EPHECT study

P38 Human biomonitoring of volatile organic compounds (VOC): Sources of error in the pre-analytical phase using the example of n-hexane

P39 Suspect Screening for Urinary Exposure Biomarkers of the Plasticizer DEHTP in a Software-Assisted LC-HRMS Approach

P40 What is the main factor determining the exposure concentration of nanoparticles in the sewer?

P41 Expert judgment in exposure assessment strategy definition – How to reduce uncertainties?

P42 Efficiency of exposure control measures – developing a User Database and Communication Tools

Exposure Science Education, Training & Communication

P43 Proposal to present the data of the Extended Safety Data exclusively in tabular form

P44 Dietary Exposure Assessment to chemicals: EFSA activities and priorities